



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 111

[Docket No. FDA-2015-N-0797]

The Food and Drug Administration Food Safety Modernization Act: Focus on Strategic Implementation of Prevention-Oriented Import Safety Programs; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing three one-day public meetings in different regions throughout the United States to provide importers and other interested persons an opportunity to have an in-depth discussion on the implementation of the FDA Food Safety Modernization Act (FSMA) import safety programs (i.e., foreign supplier verification programs (FSVPs) for importers of food for humans and animals, accreditation of third-party certification bodies, and FDA's Voluntary Qualified Importer Program (VQIP)). During these meetings, participants and key FDA subject matter experts will discuss the next phase of FSMA implementation related to import safety programs, which includes establishing the operational framework for these programs and plans for guidance documents, training, education, and technical assistance. The purpose of the regional outreach public meetings is to continue the dialogue with the importer community on FSMA and elicit ideas that will help to inform FDA and our stakeholders on how to continue to work together to successfully comply with FSMA mandates and regulations.

DATES: See section III for dates and times of the regional outreach meetings, closing dates for advance registration, and requests for special accommodations due to disability.

ADDRESSES: See section III for meeting locations.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting, or to register by phone: Peggy Walker, Planning Professionals Ltd., 1210 West McDermott St., suite 111, Allen, TX 75013, 214-384-0667, FAX: 469-854-6992, email: pwalker@planningprofessionals.com.

For general questions about the meeting or for special accommodations due to a disability:

Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 2, 2014, we released our “Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA),” electronically at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>, to guide the next phase of FSMA implementation following the establishment of regulations and relevant programs. Within the “Operational Strategy for Implementing FSMA,” there is an appendix that outlines guiding principles for how the operational strategy can be implemented with respect to food and feed facilities, produce safety standards, and import oversight. The guiding principles include the following: Expanding inspection and surveillance; administering new administrative enforcement tools; developing guidance, education, and technical assistance tools; and building a prevention-oriented import system.

On April 23, 2015, FDA hosted a public meeting as an opportunity for interested persons to share views concerning how FDA should address the operational aspects of FSMA implementation as suggested by the guiding principles. We provided an update on current planning efforts and received input from the public to inform the development of operational work plans in the areas of produce safety, preventive controls for foods for humans and animals, measures to address intentional adulteration, FSVP, and the FDA third-party accreditation program. In addition, we established a docket to obtain comments on a range of operational issues that we might consider in our FSMA implementation approach.

On March 21, 2016, FDA hosted a kick-off public meeting to brief participants on the key components of the FSVP and third-party certification final rules; brief participants on the status of the VQIP; discuss the plans for guidance documents related to import safety, as well as training, education, and technical assistance; provide an update on the development of a risk-based industry oversight framework that is at the core of FSMA; and answer questions about these import programs. The public meeting was an opportunity for FDA to share its current thinking on implementation plans for programs related to import safety. During that public meeting, we mentioned plans to continue dialogue on implementation of these import safety programs with a series of regional meeting across the United States.

The agendas, recordings, and transcripts for the FSMA implementation and prevention-oriented import system public meetings are accessible on our FSMA Web site at <http://www.fda.gov/FSMA>.

II. Purpose and Format of the Regional Outreach Meetings

FDA plans to hold three one-day public meetings in different regions throughout the United States to provide importers and other interested persons an opportunity to have an in-

depth discussion on the implementation of FSMA import safety programs (i.e., FSVPs for importers of food for humans and animals, accreditation of third-party certification bodies, and FDA's VQIP). We invite the public to provide information, share experiences, and raise issues on implementation topics related to import safety including (but not limited to): Increasing awareness/reaching the regulated community, potential partners on outreach and implementation, state of readiness, barriers to implementation, training and education for industry and regulators, guidance needs, promotion of best practices, technical assistance, compliance and enforcement issues, and long-term implementation success. The purpose of the regional outreach meetings is to continue the dialogue with the importer community and elicit ideas that will help to inform FDA and the regulated population on how to continue to work together to successfully comply with FSMA mandates and regulations.

III. How to Participate in the Public Meeting

We are holding three one-day public meetings in different regions throughout the United States.

Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the regional outreach meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is very limited.

Table 1 provides information on participation in the regional outreach meetings.

Table 1.--Information on Participation in the Meeting

Regional Outreach Meetings	Date	Address	Preregister	Electronic address	Special Accommodations	Other Information
California Regional Outreach Meeting	June 7, 2016, from 8:30 a.m. to 3 p.m. PDT	The Hilton Costa Mesa 3050 Bristol Street Costa Mesa, CA 92626	May 26, 2016: Closing date for Registration	Please preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	May 25, 2016: Closing date to request special accommodations due to a disability	Registration check-in begins at 8 a.m.
New Jersey Regional Outreach Meeting	June 15, 2016, from 8:30 a.m. to 3 p.m. EDT	Renaissance Meadowlands Hotel 801 Rutherford Avenue Rutherford, NJ 07070	June 3, 2016: Closing date for Registration	Please preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	June 2, 2016: Closing date to request special accommodations due to a disability	Registration check-in begins at 8 a.m.
Michigan Regional Outreach Meeting	June 21, 2016, from 8:30 a.m. to 3 p.m. EDT	Double Tree Suites by Hilton Hotel Detroit – Downtown Fort Shelby 525 W Lafayette Blvd. Detroit, MI 48226	June 10, 2016: Closing date for Registration	Please preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	June 9, 2016: Closing date to request special accommodations due to a disability	Registration check-in begins at 8 a.m.

¹ You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Peggy Walker, Planning Professionals Ltd., 1210 West McDermott St., suite 111, Allen, TX 75013, 214-384-0667, FAX: 469-854-6992, email: pwalker@planningprofessionals.com.

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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